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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,195	07/25/2003	William D. Ehringer	09799910.0038	2707

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,195	EHRINGER ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-17-2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims included in the prosecution are 1-27.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-5, 8-9, 13-15, 18, 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03 236320 in view of Arakawa et al (Tohoku J. Exp. Med., 1998 or Puisieux et al (Journal of Drug Targeting, 1994) both are of record, by themselves or in combination.

JP teaches wound healing compositions containing kojic acid and ATP (abstract).

What is lacking in JP is the teaching of the encapsulation of ATP in liposomes.

Arakawa teaches liposomal preparations containing encapsulated ATP. The liposomes are made from egg PC and cholesterol. According to Arakawa, such an encapsulation results in the sustained release of ATP for 90 hours (abstract, Materials and Methods).

Puisieux teaches that ATP is very sensitive to enzymatic hydrolysis and also that being hydrophilic, it is unable to cross biological membranes (abstract). Puisieux further

teaches that encapsulation of ATP in liposomes strongly increases its stability and its penetratability (pages 446-447).

The encapsulation of ATP in liposomes in the wound healing compositions of JP would have been obvious to one of ordinary skill in the art since Arakawa teaches that liposomal encapsulation would result in sustained release of ATP and since Puisieux teaches that liposomal encapsulation provides stability to ATP and its penetratability. The teachings of Arakawa,

3. Claims 4-10 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03 236320 in view of Arakawa et al (Tohoku J. Exp. Med., 1998 or Puisieux et al (Journal of Drug Targeting, 1994) by themselves or in combination as set forth above, further in view of Cullis (6,417,326).

The teachings of JP, Arakawa, and Puisieux have been discussed above, What is lacking in these references is the inclusion of polymers such as PEG or fusion proteins.

Cullis teaches that inclusion of PEG or fusion proteins in liposomes is advantageous since following the accumulation at the target site, the liposomal carrier would become fusogenic, without the need of any external stimulus, and would subsequently release any encapsulated or associated drug in the vicinity of the target cell or fuse with the target cell plasma membrane introducing the drug into the cell cytoplasm. Cullis also teaches that in certain instances, fusion of the liposomal carrier with the plasma membrane would be preferred because this would provide more specific drug delivery and, hence, minimize any adverse effects on normal, healthy cells

or tissues. Cullis's fusogenic liposomes contain claimed phospholipids and cationic lipids (note abstract, col. 2, lines 12-42; col. 10, line 9 through col. 13, line 62; col. 23, line 27 through col. 25, line 26; columns 44-50 and 53).

The inclusion of a polymer such as PEG or a fusion protein in the teachings of JP, Arakawa or Puisieux would have been obvious to one of ordinary skill in the art because of the advantages of the fusogenic liposomes in the drug delivery taught by Cullis.

4. Claims 2, 11, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03 236320 in view of Arakawa et al (Tohoku J. Exp. Med., 1998 or Puisieux et al (Journal of Drug Targeting, 1994) by themselves or in combination, in view of Cullis (6,417,326) as set forth above, further in view of Ruckert (5,863,556). The teachings of JP, Arakawa, Puisieux and Cullis have been discussed above. What is lacking in these references is the inclusion of an antiseptic or an anesthetic.

Ruckert while disclosing liposomal wound healing compositions teaches that a combination of anti-septic agents and anesthetic agents (abstract, col. 3, line 56 through col. 4, line 38 and claims).

To include an additional wound healing agent in the teachings of JP, Arakawa, Puisieux and Cullis would have been obvious to one of ordinary skill in the art with the expectation of obtaining at least an additive agent since the reference of Ruckert shows that a combination of wound healing agents could be used.

5. Claims 3, 12 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03 236320 in view of Arakawa et al (Tohoku J. Exp. Med., 1998 or Puisieux et al (Journal of Drug Targeting, 1994) by themselves or in combination, in view of Cullis (6,417,326) and Ruckert (5,863,556) as set forth above, further in view of Berthold (6,399,091).

The teachings of JP, Arakawa, Puisieux, Cullis and Ruckert have been discussed above. What is lacking in these references is the inclusion of becaplermin. The inclusion of becaplermin in the teachings of JP, Arakawa, Puisieux, Cullis would have been obvious to one of ordinary skill in the art since the reference of Berthold shows that this compound is commonly used wound healing agent (abstract and col. 3, lines 63-67) and that of Ruckert shows that a combination of wound healing agents could be used in treating wounds.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 and 35-46 of copending Application No. 10/397,048. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications recite the same vesicle compositions and a method of treating wound except that instant claims recite a wound-healing agent as an additional component besides the wound-healing agent ATP. The language 'comprising' in the claims of said copending application does not exclude an additional agent and applicant's intent in including an additional agent is evident from page 36 of the specification in said copending application. With regard to the method of delivery of ATP claims in said copending application, it is deemed obvious that instant method of treating claims include such limitation since one cannot treat without delivering the active agent. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK